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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,322	06/14/2001	Frank Robert Busch	PC10734A US	7157

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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 10/16/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	09/881,322	BUSCH ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 30* is/are pending in the application.

4a) Of the above claim(s) *8,9 and 11-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10,14-17 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's amendments filed July 31, 2003 have been entered.

Claims 1-17 and 30 are pending.

Claims 8, 9, and 11-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

The outstanding rejection of claim 14 under 35 USC 112, first paragraph is withdrawn in view of the amendments filed July 31, 2003.

Upon reconsideration, the outstanding rejection of claim 14 under 35 USC 112, second paragraph is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds recited in claims 6-17, does not reasonably provide enablement for other growth hormone secretagogue (GHS) compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In the instant case, the specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that define a "growth hormone secretagogue ". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of "growth hormone secretagogue" examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The structural differences among the compounds are great. The only common properties among these compounds are their function as growth hormone secretagogue. The

pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on **all** "growth hormone secretagogue", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Response to arguments with regard to 35 USC 112, first paragraph

Applicant's arguments filed July 31, 2003 averring the instant specification provides the criteria and sufficient guidance for one of skilled in the art to practice the instant invention have been considered, but are not found persuasive. The instant specification (p.24, line 18-21 and p.33, line 16 – p. 34, line 8) merely defines the term "growth hormone secretagouge" as any agents that can stimulate growth hormone production when administered. The claims constructively claims a method of treating SLE by employing any agents that can stimulate growth hormone secretion. Such limitation is functional. Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406:

stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first paragraph. Claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et* supra, at 468. Claims thus constructed provide no guidance as to medicaments employed, levels for providing therapeutic benefit, or provide notice for those practicing in the art, limits of protection. Simply stated, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention. Examiner notes that there is no structural relationship between the therapeutic efficacy and the compounds employed. Without such information, one of skilled in the art would be required to perform undue experimentation to identify suitable compounds for the herein claimed use.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 10, 14-17, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carpino'369 (WO97/24369 from the IDS filed July 10, 2002) and Carpino'306 (US Patent 6,107,306) in view of Hahn (Chapter 284: "Systemic Lupus Erythematosus" in Harrison's Principles of Internal Medicine, 13th ed., 1994, page 1643-1648).

Carpino'369 teaches the elected compound as the preferred growth hormone secretagogues (See the abstract and claim 90). Carpino'369 also teaches the compound can be orally administered (See page 31, line 10). Carpino'369 also teaches the compound is known to be useful to improve muscle strength and mobility as well as renal homeostasis (See page 31, line 3-4). Carpino'369 teaches the elected compound can be used with other GHS, such as GHR-6, and hexarelin, together in treating the disorders (See particularly the abstract).

Carpino'306 also teaches the same genus of compounds as Carpino'369 and those compounds are useful in treating, in addition to the above mentioned conditions, osteoporosis, improving bone remodeling, promoting cartilage formation, and treating peripheral neuropathy (See col. 27, line 16 – 21).

The references do not expressly teach the elected compound be useful in treating systemic lupus erythematosus (SLE). The references do not teach the employment of a secondary agent such as glucocorticoid, antimalarial agent, with the elected compound in the treatment of SLE.

Hahn teaches the clinical manifestation of SLE can be varied such as arthralgias, necrosis of bone, bone deformities, and peripheral neuropathy (See page 1645, Table 284-2). Hahn also teaches the antimalarial agent, quinacrine, and glucocordicoids such as prednisone, methylprednisolone, and prednisolone are useful in treating SLE (See page 1647, col. 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the elected compound to treat SLE. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a secondary agent such as glucocorticoid, antimalarial agent, with the elected compound in the treatment of SLE.

One of ordinary skill in the art would have been motivated to employ the elected compound to treat SLE because the elected compound is useful to treat the clinical manifestation of SLE such as peripheral neuropathy and renal involvement. One of ordinary skill in the art would have been motivated to employ a secondary agent such as glucocorticoid, antimalarial agent, with the elected compound in the treatment of SLE because antimalarial agent such as quinacrine and glucocorticoids such as prednisone methylprednisolone, and prednisolone are known to be useful to treat SLE. Combining and employing two or more agents which are known to be useful to treat SLE

individually into a single composition and method useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069.

Response to arguments in regard to the rejections under 35 USC 103

Applicant's arguments filed July 31, 2003 averring the cited prior art's failure to provide motivation to employ the herein claimed compounds in the treatment of SLE since treating "the specific symptom of a disease is not necessarily equivalent to the treatment of the disease itself" have been considered, but are not found persuasive. Merck Manual, a common handbook one of skilled artisan is charged to have possession, teaches that the management of SLE actually includes relieving the symptoms of SLE by NSAID (for pain) and sometimes antibiotics (for infections) (See Merck Manual, 16th ed., 1992, pages 1317-1321). Therefore, relieving symptoms of SLE by employing the herein claimed compounds is seen to be treating SLE. The claims are therefore, still properly rejected under 35 USC 103.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THEODORE J. CRIARES
PRIMARY EXAMINER
GROUP 1200
1617

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